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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,431	08/09/2001	Richard A. Mathies	A1-41US1	7455

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,431	MATHIES ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7 and 10-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7 and 10-26 as amended include a newly recited claim limitation that a vent is provided in fluid communication with the reaction chamber and "wherein the vent enables removal of gas from said reaction chamber thereby preventing a temperature variation in said liquid during said reaction". While the originally filed disclosure may support the claim limitation of a vent provided in fluid communication with the reaction chamber it does not appear to support the additional claim language "wherein the vent enables removal of gas from said reaction chamber thereby preventing a temperature variation in said liquid during said reaction". Additionally, Applicants have not pointed out where the amended and/or new claims are supported, nor does there appear to be written description of the claim limitation "wherein the vent enables removal of gas from said reaction chamber thereby preventing a temperature variation in said liquid during said reaction" in the application as filed. See M.P.E.P. 2163.04 (I).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (US 5,593,838).

The reference of Zanzucchi et al. discloses a miniature reaction chamber including a body (14) with a reaction chamber or cavity (36), a resistive heater (57) deposited within the cavity, a temperature sensor (59) for determining a temperature within the cavity. Both the heater and sensor being connected to computer controlled power supply (10).

With respect to the claimed volumes of the cavity recited in claims 8 and 9, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

Note where a claimed device and a prior art device differ only in relative dimensions and a device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See M.P.E.P. 2144.04 (IV)(A) and *In Gardner v. TEC Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984).

5. Claims 1, 2, 5, 7, 14, 16, 20, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (US 5,593,838) in view of Wilding et al.(US 5,498,392).

The reference of Zanzucchi et al. discloses a miniature reaction chamber including a body (14) with a reaction chamber or cavity (36), a resistive heater (57) deposited within the cavity, a temperature sensor (59) for determining a temperature within the cavity. Both the heater and sensor being connected to computer controlled power supply (10).

Claim 1 differs by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (16a-d) for controlling the flow of fluid into and out of the reaction chamber (22).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the reference of Zanzucchi et al. with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

With respect to claim 2, the device includes a second reaction chamber (40) fluidly connected to reaction chamber (36).

With respect to claim 5, the cavity is formed by planar members (14) and (63).

With respect to the claimed volume of the cavity recited in claim 7, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design

considerations such as the specific method or assay which is intended to be performed within the device.

Note where a claimed device and a prior art device differ only in relative dimensions and a device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See M.P.E.P. 2144.04 (IV)(A) and *In Gardner v. TEC Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984).

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 16, the reference of Zanzucchi et al. discloses the use of valves (62).

With respect to claim 20, the reference of Zanzucchi et al. discloses that the device includes at least two reaction chambers (36). Furthermore, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 23, the reference of Zanzucchi et al. discloses the use of valves (62).

6. Claims 1-5, 7 and 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (US 5,593,838) in view of Anderson et al.(US 5,922,591).

The reference of Zanzucchi et al. discloses a miniature reaction chamber including a body (14) with a reaction chamber or cavity (36), a resistive heater (57) deposited within the cavity, a

temperature sensor (59) for determining a temperature within the cavity. Both the heater and sensor being connected to computer controlled power supply (10).

Claim 1 differs by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Anderson et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (See column 25, lines 25-35 and/or Figures 2 and 5) for controlling the flow of fluid into and out of the reaction chamber (508).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the reference of Zanzucchi et al. with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

With respect to claim 2, the device includes a second reaction chamber (40) fluidly connected to reaction chamber (36).

With respect to claims 3 and 4, the reference of Anderson et al. discloses the use of additional analysis chambers that can include electrophoresis and/or probe arrays (See column 12, line 50, to column 17, line 20).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the analysis systems disclosed by Anderson et al. in with the reaction chamber of the primary reference for the known and expected result of providing an art recognized analysis system in combination with an amplification chamber of the primary reference.

With respect to claim 5, the cavity is formed by planar members (14) and (63).

With respect to the claimed volume of the cavity recited in claim 7, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

Note where a claimed device and a prior art device differ only in relative dimensions and a device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See M.P.E.P. 2144.04 (IV)(A) and *In Gardner v. TEC Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984).

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 15, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

With respect to claim 16, the reference of Zanzucchi et al. discloses the use of valves (62).

Also with respect to claims 16 and 17, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

With respect to claims 18 and 19, the reference of Anderson et al. discloses an art recognized means for introducing a sample into a microfluidic system that includes a sample introduction septum (See column 22, lines 55-67) that would been obvious to one of ordinary skill in the art to employ with the system of the primary reference as an art recognized means for introducing a sample into a microfluidic system.

With respect to claim 20, the reference of Zanzucchi et al. discloses that the device includes at least two reaction chambers (36). Furthermore, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 22, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

With respect to claim 23, the reference of Zanzucchi et al. discloses the use of valves (62).

Also with respect to claims 23 and 24, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

With respect to claims 25 and 26, the reference of Anderson et al. discloses an art recognized means for introducing a sample into a microfluidic system that includes a sample introduction septum (See column 22, lines 55-67) that would been obvious to one of ordinary skill in the art to employ with the system of the primary reference as an art recognized means for introducing a sample into a microfluidic system.

Note the reference of Anderson et al. is applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

7. Claims 6 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (US 5,593,838) in view of Anderson et al.(US 5,922,591) and Mathies et al.(US 6,132,580).

The combination of the references of Zanzucchi et al. and Anderson et al. has been discussed above.

Claim 6, differs by reciting that the temperature sensor is provided on a cover surface that the mated with a second surface including the reaction chamber.

Claims 10-13 differ by specifically reciting thermocouple materials and positioning not disclosed in the combination of the references of Zanzucchi et al. and Anderson et al.

The reference of Mathies et al. discloses that it is known in the art to provide a thermocouple positioned on one substrate forming member and the heater on the other forming member (See column 5, line 64, to column 6, line 23) when providing a heater and temperature sensor within a reaction chamber. The reference also discloses the thermocouple construction recited in claims 10-13 (See column 5, line 64, to column 6, line 42).

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with the configuration suggested by the reference of Mathies et al. for the known and expected result of providing an art recognized means for providing a heater and temperature sensor within a microfluidic reaction chamber.

Note the references of Anderson et al. and Mathies et al. are applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

8. Claims 3, 4, 18, 19, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al.(US 5,593,838) in view of Wilding et al. (US 5,498,392) and Northrup et al.(WO 94/05414) alone or alternatively further in view of Stix (Scientific American).

The combination of the references of Zanzucchi et al. and Wilding et al. has been discussed above.

The above claims further differ by reciting that the device further includes detection means that include a plurality of microcapillaries or an oligonucleotide array.

The reference of Northrup et al. discloses that it is conventional in the art to employ microelectrophoresis (See pages 4 and 10) or two-dimensional arrays (See pages 13 and 14) to detect or verify PCR products. Microfabricated devices to perform the detection procedures discussed by Northrup et al. are conventional in the art.

As a result, it would have been obvious to one of ordinary skill in the art to employ any of the well-known means in the art to detect the post-PCR products produced by the system of the primary reference. Use of microelectrophoresis or arrays of oligonucleotides would have been obvious for the known and expected result of employing an alternative means recognized in the art to achieve the same result, detection of post-PCR products.

Additionally, if the disclosure of Northrup et al. is considered to be insufficient to meet the claim limitations, the reference of Stix discloses that it is conventional in the art to link several of the well known "chip" devices so that post-PCR products are detected or verified.

As a result, it would have been obvious to one of ordinary skill in the art to link several of the well known "chip" devices (microelectrophoresis or oligonucleotide arrays) together for the

known and expected result of detecting post-PCR products as is suggested by both of the references of Northrup et al. and Stix.

With respect to claims 18, 19, 25 and 26, the reference of Northrup et al. discloses the use of septum (120) for introducing a sample into the reaction chamber (See Figure 1). As a result, it would have been obvious to one of ordinary skill in the art to provide the system of the modified primary reference to include the claimed septum member for the known and expected result of providing an art recognized means for introducing a sample into the reaction chamber of a microfluidic device.

9. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al.(US 5,593,838) in view of Wilding et al.(US 5,498,392) and Harkins (US 3,901,437).

The combination of the references of Zanzucchi et al. and Wilding et al. has been discussed above.

With respect to claim 10, while the reference of Zanzucchi et al. discloses the use of a thermocouple to sense the temperature with the reaction chamber, the reference is silent as to the use of a reference junction that is located external to the reaction chamber.

The reference of Harkins discloses that it is known in the art to provide a reference junction with a thermocouple device that it positioned so as to be exposed to the ambient temperature that is external to the environment of the sensing junction (See column 4, lines 16-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a reference junction that is external to the reaction chamber for the known and expected result of providing a means recognized in the art for compensating for variations in ambient temperature.

With respect to claim 11, while the reference of Zanzucchi et al. discloses the use of a thermocouple, the reference is silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device of the primary reference for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

10. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al.(US 5,593,838) in view of Wilding et al.(US 5,498,392) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276).

The combination of the references of Zanzucchi et al. and Wilding et al. has been discussed above.

The claims further differ by specifying that the materials of construction of the heating device and the thermocouple device.

The reference of Zdeblick discloses a microdevice which includes a heating device (20) which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to determine the optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

To further support the obviousness of the materials of construction, the reference of Loux et al. is cited as disclosing a microdevice which includes a resistive heating device which includes a trace (11) which is made of chromium and is connected to gold pads (14 and 15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ chromium and gold as materials for the temperature control system of the modified primary reference for the known and expected result of using materials which can be used in microdevices.

11. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stix (Scientific American) in view of Garner (US 5, 241,363) and Zdeblick (US 4,821,997).

The reference of Stix discloses a miniature reaction chamber which includes a heater (See the Figure).

While the reference discloses the use of a heater device within the microchamber, the reference is silent as to the use of a resistive heater temperature control system used to control or cycle the heater within the microchamber.

The reference of Garner discloses that it is well known in the art to provide a resistance heater device within a PCR or thermocycling device with a temperature sensor (thermocouple) and an appropriately programmed computer for monitoring the temperature and operating a power source to control the heater device.

The reference of Zdeblick discloses a microdevice which includes a heating device (20) which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the reference of Stix for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules.

With respect to the claimed volumes of the cavity recited in claims 7-9, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

12. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.(WO 94/05414) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997).

The reference of Northrup et al. discloses a miniature reaction device which includes at least one reaction chamber defined within a body. The reference discloses the use of heaters

(See page 2, 3, 9), a plurality of chambers within the same body (See Figure 2), electrophoretic detection means (See page 20), probe arrays (See pages 13 and 14), and lamb wave pumps and/or mixers (See page 9).

While the reference discusses the use of microheaters which include resistive heaters made as an integral part of the microstructure, the reference is silent as to the specifics of the temperature control of the microheating device. Specifically, independent claim 1 requires the use of a temperature sensor provided within the cavity and a programmed computer connected to the heater and sensor.

The reference of Garner discloses that it is well known in the art to provide a resistance heater device within a PCR or thermocycling device with a temperature sensor (thermocouple) and an appropriately programmed computer for monitoring the temperature and operating a power source to control the heater device.

The reference of Zdeblick discloses a microdevice which includes a heating device, 20, which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the reference the modified primary reference for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules.

With respect to the claimed volumes of the cavity recited in claims 7-9, while the reference does not specifically recite the volume of the disclosed cavities, it would have been

obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

13. Claims 1-5, 7, 12-14, 16, 18-21, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.(WO 94/05414) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276) taken further in view of Wilding et al.(US 5,498,392).

The combination of the references of Northrup et al., Garner and Zdeblick has been discussed above.

Claim 1 differs by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (16a-d) for controlling the flow of fluid into and out of the reaction chamber (22).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the reference of Northrup et al. with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

Additionally with respect to the materials of the heater and thermocouple recited in claims 12 and 13, it would have been obvious to one of ordinary skill in the art to determine the

optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

To further support the obviousness of the materials of construction, the reference of Loux et al. is cited as disclosing a microdevice which includes a resistive heating device which includes a trace, 11, which is made of chromium and is connected to gold pads, 14 and 15.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ chromium and gold as materials for the temperature control system of the modified primary reference for the known and expected result of using materials which can be used in microdevices.

With respect to the claimed volumes of the cavity recited in claim 7, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

Note where a claimed device and a prior art device differ only in relative dimensions and a device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See M.P.E.P. 2144.04 (IV)(A) and *In Gardner v. TEC Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984).

With respect to claims 2-4, see pages 13, 14 and 20 of Northrup et al. which disclose the use of electrophoresis detection and probe arrays.

With respect to claim 5, see the substrate construction shown in Figure 3 of Northrup et al.

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 16, the disclosed micropumps function as valves.

With respect to claims 18, 19, 25 and 26, the reference of Northrup et al. discloses the use of septum (120) for introducing a sample into the reaction chamber (See Figure 1).

With respect to claim 20, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 23, the disclosed micropumps function as valves.

14. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.(WO 94/05414) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276) and Wilding et al.(US 5,498,392) taken further in view of Harkins (US 3,901,437).

The combination of the references of Northrup et al. with Garner and Zdeblick alone or further in view of Loux et al. taken further in view of Wilding et al. has been discussed above.

With respect to claim 10, while the modified primary reference suggests the use of a thermocouple to sense the temperature with the reaction chamber, the reference is silent as to the use of a reference junction that is located external to the reaction chamber.

The reference of Harkins discloses that it is known in the art to provide a reference junction with a thermocouple device that it positioned so as to be exposed to the ambient

temperature that is external to the environment of the sensing junction (See column 4, lines 16-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a reference junction that is external to the reaction chamber for the known and expected result of providing a means recognized in the art for compensating for variations in ambient temperature.

With respect to claim 11, while the modified primary reference suggests the use of a thermocouple, the reference is silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device of the primary reference for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

15. Claims 1-5, 7 and 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.(WO 94/05414) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276) taken further in view of Anderson et al.(US 5,922,591).

The combination of the references of Northrup et al., Garner and Zdeblick has been discussed above.

Claim 1 differs by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Anderson et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (See column 25, lines 25-35 and/or Figures 2 and 5) for controlling the flow of fluid into and out of the reaction chamber (508).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the reference of Northrup et al. with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

With respect to claims 2-4, see pages 13, 14 and 20 of Northrup et al. which disclose the use of electrophoresis detection and probe arrays.

With respect to claim 5, see the substrate construction shown in Figure 3 of Northrup et al.

With respect to the claimed volume of the cavity recited in claim 7, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

Note where a claimed device and a prior art device differ only in relative dimensions and a device having the claimed dimensions would not perform differently than the prior art device,

the claimed device is not patentably distinct from the prior art device. See M.P.E.P. 2144.04 (IV)(A) and *In Gardner v. TEC Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984).

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 15, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

With respect to claim 16, the disclosed micropumps function as valves.

With respect to claims 18, 19, 25 and 26, the reference of Northrup et al. discloses the use of septum (120) for introducing a sample into the reaction chamber (See Figure 1).

With respect to claim 20, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 22, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

With respect to claim 23, the disclosed micropumps function as valves.

Also with respect to claims 16 and 17, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

Note the reference of Anderson et al. is applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

16. Claims 6 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.(WO 94/05414) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276) and Anderson et al.(US 5,922,591) taken further in view of Mathies et al.(US 6,132,580).

The combination of the references of Northrup et al., Garner, Zdeblick and Anderson et al. has been discussed above.

Claim 6, differs by reciting that the temperature sensor is provided on a cover surface that the mated with a second surface including the reaction chamber.

Claims 10-13 differ by specifically reciting thermocouple materials and positioning not disclosed in the combination of the references discussed above.

The reference of Mathies et al. discloses that it is known in the art to provide a thermocouple positioned on one substrate forming member and the heater on the other forming member (See column 5, line 64, to column 6, line 23) when providing a heater and temperature sensor within a reaction chamber. The reference also discloses the thermocouple construction recited in claims 10-13 (See column 5, line 64, to column 6, line 42).

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with the configuration suggested by the reference of Mathies et al. for the known and expected result of providing an art recognized means for providing a heater and temperature sensor within a microfluidic reaction chamber.

Note the references of Anderson et al. and Mathies et al. are applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,284,525 in view of Northrup et al.(wo 94/05414) or Zanzucchi et al.(US 5,593,838) taken further in view of Wilding et al.(US 5,498,392) or Anderson et al.(US 5,922,591). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,284,525 encompasses substantially the same device, the instant claims recite a "resistive heater" while the patented claims merely recite a "heater".

The references of Northrup et al. (See page 9, lines 29-32) and Zanzucchi et al.(See Figure 4B) both disclose that the use of resistive heaters are known in the art for heating the contents of a reaction chamber in a microfluidic device.

As a result, it would have been obvious to one of ordinary skill in the art to employ a resistive heater in the system encompassed by the patented claims for the known and expected result of providing a heater device recognized in the art for heating and/or controlling the temperature within a microfluidic reaction chamber.

Claim 1 differs further by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (16a-d) for controlling the flow of fluid into and out of the reaction chamber (22).

The reference of Anderson et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (See column 25, lines 25-35 and/or Figures 2 and 5) for controlling the flow of fluid into and out of the reaction chamber (508).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the patented claims with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

With respect to claim 2, see patented claims 1, 8, 10 and 11.

With respect to claim 3, see patented claims 1, 8, and 10.

With respect to claim 4, see patented claim 11.

With respect to claim 5, see patented claim 12.

With respect to claim 6, see patented claims 7 and 9.

With respect to claims 7-9, see patented claims 13-15.

With respect to claim 10, see patented claim 16.

With respect to claim 11, see patented claim 17.

With respect to claim 12, see patented claim 18.

With respect to claim 13, see patented claim 19.

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 16, the disclosed micropumps function as valves.

With respect to claims 18, 19, 25 and 26, the reference of Northrup et al. discloses the use of septum (120) for introducing a sample into the reaction chamber (See Figure 1).

With respect to claim 20, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 22, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

With respect to claim 23, the disclosed micropumps function as valves.

Also with respect to claims 16 and 17, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

Note the reference of Anderson et al. is applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

19. Claims 1-5 and 7-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,132,580 in view of Northrup et al.(wo 94/05414) or Zanzucchi et al.(US 5,593,838) taken further in view of Wilding et al.(US 5,498,392) or Anderson et al.(US 5,922,591). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,132,580 encompasses substantially the same device, the instant claims recite a "resistive heater" while the patented claims merely recite a "heater".

The references of Northrup et al. (See page 9, lines 29-32) and Zanzucchi et al.(See Figure 4B) both disclose that the use of resistive heaters are known in the art for heating the contents of a reaction chamber in a microfluidic device.

As a result, it would have been obvious to one of ordinary skill in the art to employ a resistive heater in the system encompassed by the patented claims for the known and expected result of providing a heater device recognized in the art for heating and/or controlling the temperature within a microfluidic reaction chamber.

Claim 1 differs further by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (16a-d) for controlling the flow of fluid into and out of the reaction chamber (22).

The reference of Anderson et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (See column 25, lines 25-35 and/or Figures 2 and 5) for controlling the flow of fluid into and out of the reaction chamber (508).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the patented claims with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

With respect to claim 2, see patented claims 1 and 2.

With respect to claim 3, see patented claim 1.

With respect to claim 4, see patented claim 2.

With respect to claim 5, see patented claim 3.

With respect to claims 7-9, see patented claims 9-11.

With respect to claim 10, see patented claim 12.

With respect to claim 11, see patented claim 13.

With respect to claim 12, see patented claim 14.

With respect to claim 13, see patented claim 16.

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 16, the disclosed micropumps function as valves.

With respect to claims 18, 19, 25 and 26, the reference of Northrup et al. discloses the use of septum (120) for introducing a sample into the reaction chamber (See Figure 1).

With respect to claim 20, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 22, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

With respect to claim 23, the disclosed micropumps function as valves.

Also with respect to claims 16 and 17, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

Note the reference of Anderson et al. is applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

20. Claims 1-9, 12 and 14-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,261,431 in view of Wilding et al.(US 5,498,392) or Anderson et al.(US 5,922,591). Although the conflicting claims are not identical, they are not patentably distinct from each other because the combination of a heater that is a resistive heater and the use of a computer to monitor and control a power source for the heater recited in claim 1 of the instant claims is not includes as a combination of elements in a single claim of the patented claims. However, patented claim 6 discloses the use of a resistive heater and patented claim 17 discloses the use of a controller for controlling the temperature of the reactions chamber. As a result, it would have been obvious to

one of ordinary skill in the art to employ both the resistive heater and controller as suggested by the claimed to define a device that is the same as that required of instant claim 1.

Claim 1 differs further by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (16a-d) for controlling the flow of fluid into and out of the reaction chamber (22).

The reference of Anderson et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (See column 25, lines 25-35 and/or Figures 2 and 5) for controlling the flow of fluid into and out of the reaction chamber (508).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the patented claims with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

With respect to claim 2, see patented claims 1 and 14.

With respect to claim 3, see patented claim 1.

With respect to claim 4, see patented claim 14.

With respect to claim 5, see patented claim 1.

With respect to claim 6, see patented claim 10.

With respect to claims 7-9, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

With respect to claim 12, see patented claim 16.

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 15, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

Also with respect to claims 16 and 17, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

With respect to claims 18 and 19, the reference of Anderson et al. discloses an art recognized means for introducing a sample into a microfluidic system that includes a sample introduction septum (See column 22, lines 55-67) that would been obvious to one of ordinary skill in the art to employ with the system of the primary reference as an art recognized means for introducing a sample into a microfluidic system.

With respect to claim 20, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 22, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

Also with respect to claims 23 and 24, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

With respect to claims 25 and 26, the reference of Anderson et al. discloses an art recognized means for introducing a sample into a microfluidic system that includes a sample introduction septum (See column 22, lines 55-67) that would been obvious to one of ordinary skill in the art to employ with the system of the primary reference as an art recognized means for introducing a sample into a microfluidic system.

Note the reference of Anderson et al. is applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

21. Claims 10 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,261,431 in view of Wilding et al.(US 5,498,392) or Anderson et al.(US 5,922,591) taken further in view of Harkins (US 3,901,437). The device encompassed by claims 1-17 of U.S. Patent No. 6,261,431 has been discussed above.

With respect to claim 10, while the patented claims suggest the use of a thermocouple to sense the temperature with the reaction chamber, the patented claims are silent as to the use of a reference junction that is located external to the reaction chamber.

The reference of Harkins discloses that it is known in the art to provide a reference junction with a thermocouple device that it positioned so as to be exposed to the ambient

temperature that is external to the environment of the sensing junction (See column 4, lines 16-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system encompassed by the patented claims with a reference junction that is external to the reaction chamber for the known and expected result of providing a means recognized in the art for compensating for variations in ambient temperature.

With respect to claim 11, while the patented claims suggest the use of a thermocouple, the reference is silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device encompassed by the patented claims for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

22. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,261,431 in view of Wilding et al.(US 5,498,392) or Anderson et al.(US 5,922,591) taken further in view of Zdeblick (US 4,821,997). The device encompassed by claims 1-17 of U.S. Patent No. 6,261,431 has been discussed above.

With respect to claim 13, while the patented claims suggest the use of a thin film resistive heater, they do not disclose the use of a chromium film with gold leads.

The reference of Zdeblick discloses a microdevice which includes a heating device, 20, which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the device encompassed by the patented claims for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules. Additionally with respect to the materials of the heater 13, it would have been obvious to one of ordinary skill in the art to determine the optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

23. Claims 1-9 and 11-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-20 of copending Application No. 09/906,411 in view of Garner (US 5, 241,363) and Zdeblick (US 4,821,997) taken further in view of Wilding et al.(US 5,498,392) or Anderson et al.(US 5,922,591).

Claims 1-3 and 5-20 of application '411 encompass a device that is substantially the same as that recited in claims 1-9, 12 and 13 of the instant application.

While the claims of application '411 encompass the use of microheaters which include resistive heaters made as an integral part of the microstructure, the reference is silent as to the specifics of the temperature control of the microheating device. Specifically, independent claim

1 requires the use of a temperature sensor provided within the cavity and a programmed computer connected to the heater and sensor.

The reference of Garner discloses that it is well known in the art to provide a resistance heater device within a PCR or thermocycling device with a temperature sensor (thermocouple) and an appropriately programmed computer for monitoring the temperature and operating a power source to control the heater device.

The reference of Zdeblick discloses a microdevice which includes a heating device, 20, which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the device encompassed by the claims of application '411 for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules. Additionally with respect to the materials of the heater and thermocouple recited in claims 12 and 13, it would have been obvious to one of ordinary skill in the art to determine the optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

Claim 1 differs further by reciting that the device includes a vent provided in fluid communication with the reaction chamber.

The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (16a-d) for controlling the flow of fluid into and out of the reaction chamber (22).

The reference of Anderson et al. discloses that it is known in the art to provide a microfluidic device with vents/ports (See column 25, lines 25-35 and/or Figures 2 and 5) for controlling the flow of fluid into and out of the reaction chamber (508).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the reaction chamber of the patented claims with a vent for the known and expected result of providing an art recognized means for controlling the flow of liquid into and out of the reaction chamber. In the absence of further positively recited structure in the claims, the vent would be capable of providing the claimed function of preventing temperature variation.

With respect to claim 2, see claims 1, 5 and 15 of application '411.

With respect to claim 3, see claims 1 and 5 of application '411.

With respect to claim 4, see claim15 of application '411.

With respect to claim 5, see claims 16 of application '411.

With respect to claim 6, see claim 17 of application '411.

With respect to claims 7-9, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

With respect to claim 10, see claim 18 of application '411.

With respect to claim 12, see claim 19 of application '411.

With respect to claim 14, the reaction chamber is capable of performing PCR.

With respect to claim 15, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

Also with respect to claims 16 and 17, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

With respect to claims 18 and 19, the reference of Anderson et al. discloses an art recognized means for introducing a sample into a microfluidic system that includes a sample introduction septum (See column 22, lines 55-67) that would been obvious to one of ordinary skill in the art to employ with the system of the primary reference as an art recognized means for introducing a sample into a microfluidic system.

With respect to claim 20, it is well established that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See M.P.E.P. 2144.04 (VI)(B) and *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 21, the reaction chamber is capable of performing PCR.

With respect to claim 22, the reference of Anderson et al. discloses covering the vent opening with a hydrophobic material (See Figure 2B).

Also with respect to claims 23 and 24, the reference of Anderson et al. discloses alternative means recognized in the art for controlling the flow into and out of a chamber that includes a diaphragm valve (114).

With respect to claims 25 and 26, the reference of Anderson et al. discloses an art recognized means for introducing a sample into a microfluidic system that includes a sample introduction septum (See column 22, lines 55-67) that would been obvious to one of ordinary

skill in the art to employ with the system of the primary reference as an art recognized means for introducing a sample into a microfluidic system.

Note the reference of Anderson et al. is applicable as prior art since the instant claims at best have an effective filing date of 09 Aug. 2000 in view of the newly recited claim limitations.

This is a provisional obviousness-type double patenting rejection.

24. Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-20 of copending Application No. 09/906,411 in view of Garner (US 5, 241,363), Zdeblick (US 4,821,997) and Wilding et al.(US 5,498,392) or Anderson et al.(US 5,922,591) taken further in view of Harkins (US 3,901,437).

The combination of claims 1-3 and 5-20 of copending application '411 with Garner and Zdeblick with either Wilding et al. or Anderson et al. has been discussed above.

With respect to claim 11, while claims encompassed by application '411 suggest the use of a thermocouple, these claims are silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device encompassed by the claims of application '411 for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

This is a provisional obviousness-type double patenting rejection.

25. Claims 1-26 are directed to an invention not patentably distinct from claims 1-36 of commonly assigned Patent No. 6,284,525. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the obviousness-type double patenting rejection above.

26. Claims 1-5 and 7-26 are directed to an invention not patentably distinct from claims 1-27 of commonly assigned Patent No. 6,132,580. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the obviousness-type double patenting rejection above.

27. Claims 1-26 are directed to an invention not patentably distinct from claims 1-17 of commonly assigned Patent No. 6,261,431. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the obviousness-type double patenting rejections above.

28. Claims 1-26 are directed to an invention not patentably distinct from claims 1-3 and 5-20 of commonly assigned application 09/906,411. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the provisional obviousness-type double patenting rejections above.

29. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent Nos. 6,132,580 and 6,284,525, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Response to Arguments

30. Applicant's arguments filed 06 Feb. 2004 have been fully considered but they are not persuasive.

With respect to claims 1, 2 and 5, Applicants argue (See page 7, second paragraph) that the rejection of these claims over the reference of Zanzucchi et al. is not proper because the reference of Zanzucchi et al. does not disclose a microfluidic device with a cavity and a body

that includes at least first and second planar members wherein the first member includes a well disposed in the first surface and the second planar member has a planar surface that mates with the first planar member with the well to form a cavity.

Applicants comments are not persuasive because the reference of Zanzucchi et al. clearly displays this claimed construction as shown in Figure 5B which includes a first planar member (48) with a well (36) and a second planar member (63). Furthermore, only claim 5 was limited to this type of structure. Claim 1 is silent as to the use of planar members to form the cavity.

With respect to the location of the temperature sensor, the reference of Zanzucchi et al. was not relied upon to disclose this claim limitation set forth in claim 6. Again, claim 1 is silent as to this claim limitation.

With respect to claims 7-9, Applicants argue that the rejection of these claims (See page 7, third paragraph) is improper because "Applicants believe that they are the first to successfully design such microfluidic device with a reaction chamber capable of handling, transferring and processing such small volumes for successfully performing reactions in the reaction chamber".

In response, it is well established that where a claimed device and a prior art device differ only in relative dimensions and a device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See M.P.E.P. 2144.04 (IV)(A) and *In Gardner v. TEC Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984). In this case, the device of the reference of Zanzucchi et al. is a microfluidic device performing the same processing steps as the instant invention. As a result, the device made of the claimed dimensions would not perform differently than the device of the reference of Zanzucchi et al. Furthermore, the reference of Northrup et al.(WO 94/05414) clearly

establishes that microfluidic devices with chambers in volume ranging from microliters to nanoliters (See page 14, lines 33-35) is not a novel concept.

With respect to Applicants' comments concerning the new claim limitations of independent claim 1 and new claims 14-26, the instant office action addresses these new claim limitations.

It is also noted that Applicants' response filed 06 Feb. 2004 does not respond to the prior art rejections of record with respect to the combination of references that do not include the reference of Zanzucchi et al. Furthermore, Applicants' response filed 06 Feb. 2004 does not respond to the obviousness-type double patenting rejections of record.

For these reasons, Applicants' comments are not found to be persuasive and the claims remain rejected over the prior art of record.

Conclusion

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

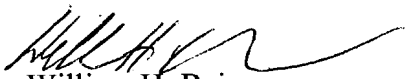
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB